DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Rayence Co, Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

March 10, 2015

Re: K143753
Trade/Device Name: EzSensor Soft [Alternative name : EzSensor Bio] digital dental image processing system
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: February 16, 2015
Received: February 23, 2015

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K143753

Device Name
EzSensor Soft [Alternative name : EzSensor Bio] digital dental image processing system

Indications for Use *(Describe)*

EzSensor Soft [Alternative name : EzSensor Bio] Digital Dental Intra Oral Sensor is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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1. 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510K summary prepared: February 16, 2015

Submitter's Name, address, telephone number, a contact person:

Submitter's Name :	Rayence Co., Ltd.
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Submitter's Telephone:	+82-31-8015-6459
Contact person:	Mr. Kee Dock Kim / RA Team Manager / +82-31-8015-6459
Official Correspondent:	Dave Kim **(**davekim@mtech-inc.net**)**
(U.S. Designated agent)	
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Telephone:	+713-467-2607
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Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Trade/proprietary name:	EzSensor Soft [Alternative name : EzSensor Bio]
Common Name:	Digital Dental Intra Oral Sensor
Regulatoin number:	21 CFR 872.1800
Regulation name:	Extraoral source X-ray system
Product Code:	MUH

Predicate Device :

Manufacturer	: Rayence Co., Ltd.
Device	: EzSensor
510(k) Number	: K090526 (Decision Date – DEC. 2. 2009)

2. Device Description

EzSensor Soft[Alternative name : EzSensor Bio] Digital Dental Intra Oral Sensor is a device which acquires digital intra oral images. Direct digital systems acquire images with a flexible sensor that is connected to a computer to produce an image almost instantaneously following exposure. The primary advantage of direct sensor systems is the speed with which images are acquired. For patient comfort, the ergonomic design is based on human intraoral anatomy.

- Excellent image quality based on advanced CMOS technology
- Sensor's ergonomic shape is more comfortable for the human oral structure
- Lower dose exposure (compared to film sensor)
- Enhanced durability
- Easy-to-use USB interface

3. Indication for use

EzSensor Soft [Alternative name : EzSensor Bio] Digital Dental Intra Oral Sensor is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists.

4. Summary of Design Control Risk management

The risks and the hazardous impact of the device modification were analyzed with FMEA method. The specific risk control and protective measures to mitigate the risks from the modification were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and hazardous conditions identified arising from the design change were successfully mitigated and accepted.

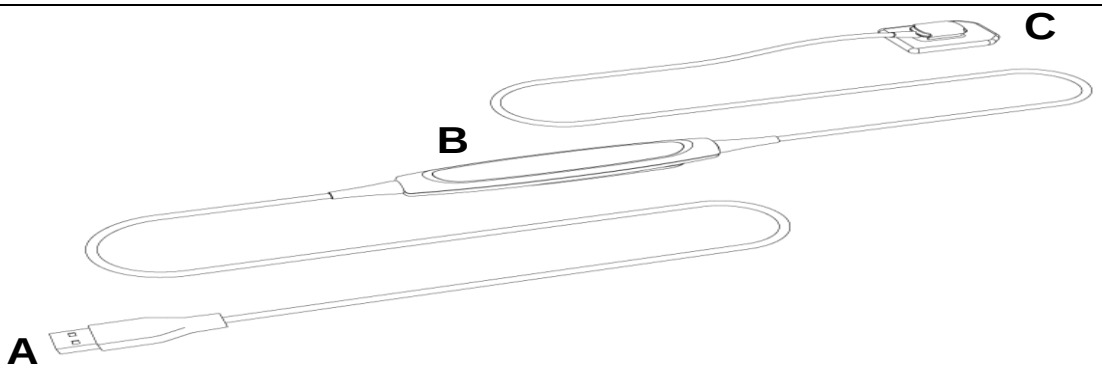
5. Summary of the technological characteristics of the device compared to the predicate device

The EzSensor Soft [Alternative name : EzSensor Bio] Digital Dental Intra Oral Sensor described in this 510(k) has the same indications for use and similar technical characteristics as its predicate device, EzSensor of Rayence Co., Ltd.

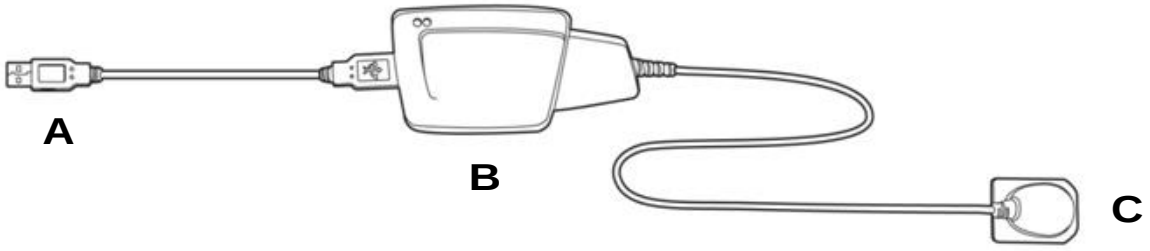
5. 1 Feature

The mechanical design for each device is different as following.

Proposed : EzSensor Soft [Alternative name : EzSensor Bio]



Predicate : EzSensor



A : USB Port **B** : Interface Board **C** : Sensor

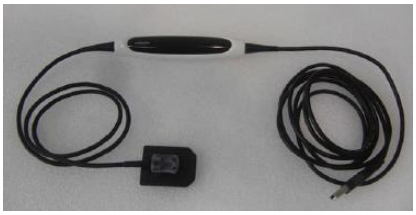
Differences

	Proposed	**Predicate**
B	1) Improved the user grip by designing the interface board housing slim to reduce the possibility of dropping the sensor. 2) The holder for the sensor housting makes it easily portable.	The interface board is larger.
C	Soft silicon material surrounds the moudule to reduce the discomfort when it is positioned inside the mouth compared to the predicate device.	The aluminum case caused a pain and discomfort when it was placed inside the mouth of a patient.

EzSensor Soft [Alternative name : EzSensor Bio] The potential risks (electroic shock, device failure, misdiagnosis, tissue damage, serious leakage current, etc…) were analyzed by conducting complete verification for IEC/EN 60601-1 and drop & vibration test. (Completed the risk analysis for A,B,C above).

While applying the sensor exterior with soft silicon material reduced the oral discomfort or pain, additional risk analysis was conducted to mitigate the potential risks that may arise with respect to leakage current, sensor fracture or breakage, and cable disconnection. The risk mitigation measures were satisfactory to manage the new risks identified and the residual risks were within acceptable limits.

5. 2 Characteristic

Characteristic	**Proposed** **Rayence Co., Ltd.** **EzSensor Soft** **[Alternative name : EzSensor Bio]**	**Predicate** **Rayence Co., Ltd.** ***EzSensor***
Feature		
510(k) number	K150212	K090526
Indications for use	EzSensor Soft [Alternative name : EzSensor Bio] Digital Dental Intra Oral Sensor is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists.	EzSensor, an Intra-oral Imaging System, is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.
Sensor Dimension(mm)	Size “1.0”: 37.5 x 26.5 Size “2.0”: 43.5 x 32.5	Size “1.0”: 35.7 x 25.2 Size “1.5”: 38.7 x 29.2
Sensor Thickness	5	4.9
Active Area(mm)	Size “1.0”: 20 x 30 Size “2.0”: 25.99 x 35.99	Size “1.0”: 20.02 x 30.03 Size “1.5”: 24.08 x 31.85
Pixel Pitch(㎛)	14.8	35
SB Module	Integrated USB 2.0 module	Integrated USB 2.0 module
	Full Resolution 14.8	35

Pixel Pitch(㎛)	Binning Mode	29.6	
DQE(6 lp/mm)	Full Resolution	0.199	0.123
	Binning Mode	0.199	
MTF(6 lp/mm)	Full Resolution	0.436	0.382
	Binning Mode	0.464	
Typical dose range(μGy)	Incisor & Canine : 300 ~ 500 / Molar: 400 ~ 600		
Active Pixel Array	Size 1.0: 1352 x 2028 pixels (30 x 20 mm) 676 x 1014 pixels @ binning mode Size 2.0: 2432 x 1756 pixels (35.99 x 25.99 mm) 1216 x 878 pixels @ binning mode		Size 1.0: 572 x 858 pixels (20.02 x 30.03 mm) Size 1.5: 686 x 944 pixels (24.01 x 33.04 mm)

5. 3 Viewer Software

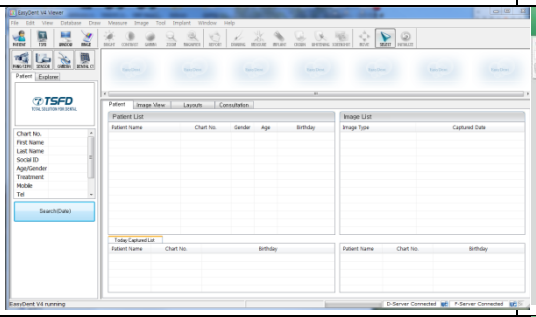
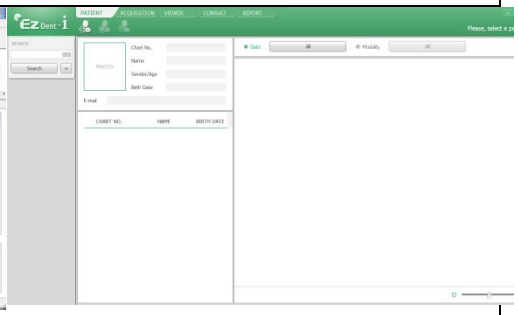
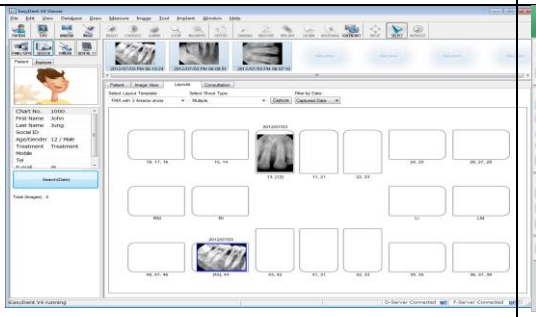
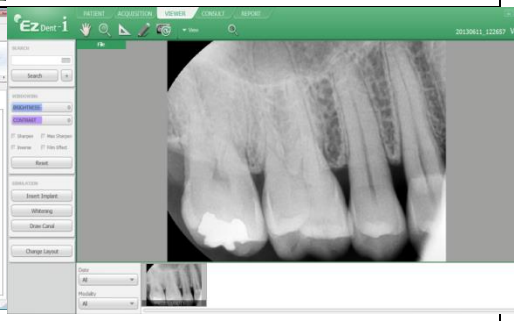
Characteristic	**Proposed** **Rayence Co., Ltd.** **EzSensor Soft** **[Alternative name : EzSensor Bio]**	**Predicate** **Rayence Co., Ltd.** ***EzSensor***
Viewer Software	Easydent & EzDent i	Easydent

This device is operated using viewer software. With the identical hardware configuration, the model name is distinguished by the type of image viewing software available. The software functions include the patient information management, image capture, and viewer for captured images.

Viewer Software	**510(k) Number**	**Manufacturer**
Easydent	-	Rayence Co., Ltd.
EzDent i	K131594	EWOO SOFT

Easydent and EzDent i image viewing software have the same functionality and performance. The main difference is the design of the user interface (UI) and new consulting simulation tool for EzDent i. EzDent i requires a fee based license registration for the right to use whereas Easydent is provided free of charge.

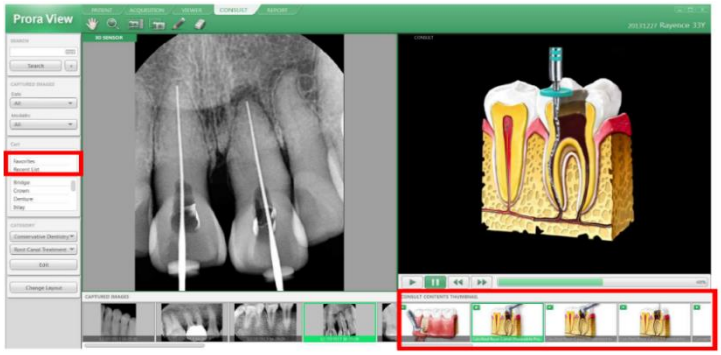
5.4 Difference for Easydent and EzDent i

	Easydent	**EzDent i**
Function	Patient View Acquisition Consultation Report	Patient View **Acquisition** Consultation Report **License**
The initial screen shot		
Image Acquisition screen		

5.5 Features added to EzDent i

5.5.1. Acquisition_ **CONSULT Tab**

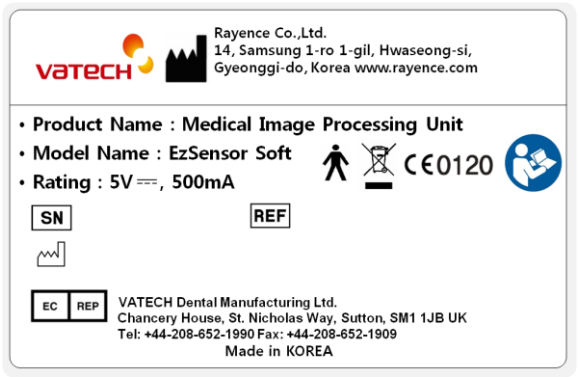
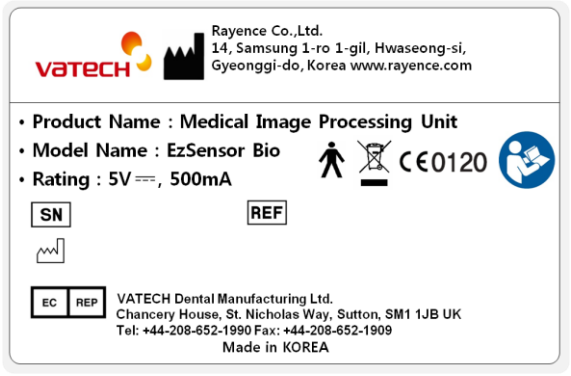
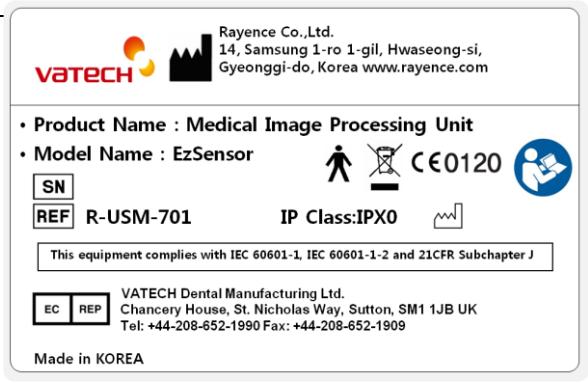
Acquisition_ **CONSULT Tab** is a consulting tool and provides a video simulation of the treatment process with the acquired images in sequence.



5.5.2. **License**

EzDent i requires a fee based license registration for the right to use whereas EasyDent is provided free of charge.

6. Proposed Labeling- Changes in comparison to the predicate device

Proposed **Rayence Co., Ltd.** **EzSensor Soft** **[Alternative name : EzSensor Bio]**	**Predicate** **Rayence Co., Ltd.** ***EzSensor***
 	

7.Summary of Performance Testing

The intended use, application and detector type of EzSensor Soft[Alternative name : EzSensor Bio] is the same as that of the predicate device, EzSensor. Both EzSensor Soft[Alternative name : EzSensor Bio] and EzSensor use the same amorphous silicon alley and materials for fluorescent as the sensing means. The performance test result indicates that the EzSensor Soft[Alternative name : EzSensor Bio] detector outperformed EzSensor (the predicated device) in terms of DQE, MTF, and NPS. No additional safety risk is identified in the bench test: SSXI report.

With a smaller measured pixel size of EzSensor Soft, both in full resolution and in 2x2 binning mode, DQE, MTF, and NPS test demonstrated that EzSensor Soft has better performance results than EzSensor, the predicate sensor.
Especially, the response of EzSensor Soft (alternatively, EzSensor Bio) as a function of X-ray exposure is very linear and has better linearity than EzSensor in the same dynamic range.

The EzSensor Soft intra oral sensor improved the noise performance and superior CNR characteristics compared to EzSensor, the predicate device. Lower the contrast-to-noise ratio (CNR), it is less able to represent a fine shade of the lesion. The superior CNR performance of EzSensor Soft compared to EzSensor is the direct result of the Noise improvement.

The pixel pitch of EzSensor Soft(Proposed) is smaller than one for EzSensor(Predicate) and the difference between the resolution is expected to be large. However, final images generated by both new and predicate sensors are subject to post processing (image enchangement) image optimization with the noise improvement and maximization of signal-to-noise ratio. Therefore the new sensor images are similar or moderatly superior to existing EzSensor (Predicate).

Total 30 sets of radiographic images were reviewed by a licensed dentist. Based on the reviewer's conclusion, EzSensor Soft[Alternative name : EzSensor Bio] (Full Resolution Mode) more closely matches EzSensor. In addition, images of EzSensor Soft[Alternative name : EzSensor Bio] in full resolution mode is generally more sharper and clearer than EzSensor Soft[Alternative name : EzSensor Bio] in binning mode.

All images present no difficulty in evaluating a range of antomic structures necessary to provide a correct conclusion while minimizing radiation exposure to patients.

Clinical images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device. However they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended.

9. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Rayence Co., Ltd. concludes that EzSensor Soft [Alternative name : EzSensor Bio] is safe and effective and substantially equivalent to predicate device as described herein.